Author's response to reviews

Title: Foot orthoses for the prevention of lower limb overuse injuries in naval recruits: study protocol for a randomised controlled trial

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Title: Foot orthoses for the prevention of lower limb overuse injuries in naval recruits: study protocol for a randomised controlled trial

Authors: Daniel R Bonanno, George S Murley, Shannon E Munteanu, Karl B Landorf, Hylton B Menz

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Dear Dr Alan Borthwick,

We would like to thank you and the two reviewers for the critical appraisal related to this manuscript. We have provided our response directly below each point that has been raised by the reviewers. We hope we have satisfactory addressed all issues raised and look forward to any further feedback/suggestions as part of the Journal of Foot and Ankle Research editorial review process.

Kind regards,

Daniel R Bonanno, George S Murley, Shannon E Munteanu, Karl B Landorf and Hylton B Menz
1. Is the question posed original, important and well defined?

**Reviewer comment:** The area is of importance but initially is limited to the specific sample group under investigation, namely naval recruits. Therefore, any potential extrapolation should be treated cautiously but it appears this is recognised in the submitted article. Further detail is required as to the definition of the proposed orthotic intervention as there does not appear to be a prescriptive/functional element to separate it from that of a simple insole.

Consequently, the proposed question would not match the study design.

**Authors’ response:** We agree that generalising the findings to populations beyond naval recruits will require caution. As the reviewer has acknowledged, we have recognised this and have already considered it in detail in the manuscript (refer to the final paragraph of the discussion). Also, the population being studied (naval recruits) is clearly stated in the title.

The orthotic intervention used in this trial meets the Prescription Foot Orthotic Laboratory Association (PFOLA, http://www.pfola.org/) definition of a foot orthosis as it is ‘an in shoe device that braces, supports, or protects the foot or part of the foot’. Further, this product is marketed as a ‘foot orthotic’ by the manufacturer and similar Formthotics® foot orthoses have been referred to as an orthotic intervention in peer-reviewed publications [1-6]. Finally, Formthotics® foot orthoses have been used in biomechanical studies and have been shown to affect lower limb biomechanics [3-6] so the authors propose that the term ‘foot orthoses’ accurately reflects the intervention under investigation and it should not be considered as a ‘simple insole’.

2. Are the data sound and well controlled?

**Reviewer comment:** Some justification as to why a cross over design would be not beneficial as it would appear that participants will be able to identify the difference in intervention, thus querying the claim of a “blind” RCT. This statement is underpinned by the fact that the participants will be living and working in close proximity and the visual difference between the control and intervention maybe apparent.

Moreover, the reviewer was unsure from the manuscript if the flat insoles were also to be heat moulded (see text on pp 8 of the article). Therefore, clarification of this point would be essential to differentiate between the validity of a control and intervention. Namely, is the difference due to a presence or absence of a medial arch support as the material and density appear to be identical? The reviewer would also like to know if the protocol allowed for data to be captured any potential participant visits to the medical officer or physio during the trial period.

**Authors’ response:** A randomised controlled trial is considered the gold-standard for testing the effectiveness of an intervention. Accordingly, a randomised controlled trial is a superior study design in comparison to a cross-over design to test our study’s aim. Regarding the use of the control intervention, we have ensured that the interventions look as similar as possible (same colour, material, branding, packaging, heat-moulding etc.). The participants were advised that they were volunteering for an ‘insole study’ and they were under the understanding that the study was testing different ‘shoe insoles’ during the study. The interventions (foot orthoses and flat insoles) were only...
referred to as ‘shoe insoles’ to the participants – they were not advised that the study was investigating ‘foot orthoses’ and ‘control insoles’. In addition, recruits are asked to rate the credibility and expected benefit of the shoe insoles that they were allocated to (this should assist with measuring blinding). As mentioned in the discussion, we agree that there is the potential for participants to compare shoe insoles as they reside within the same barracks and may notice differences between them. However, as all insoles have the same branding, are made from the same material and will be heat moulded to the participant’s feet, they are intended to look as similar as possible. Also, even if participants were able to distinguish differences between insoles, they were only made aware that the study was investigating different ‘shoe insoles’.

Regarding paragraph 2 above, as stated in the methods and discussion, both interventions (orthoses and flat insoles) will be heat moulded. To clarify this point further, we have provided additional information regarding this. It now reads as: ‘The allocated shoe insoles (flat insole or prefabricated foot orthosis) will be placed in the participant’s footwear and heat moulded to the participant’s feet and footwear. To achieve this, the participants will receive their footwear containing their heated insoles and they will be required to stand in them to enable the insoles to mould to their feet, as per the manufacturer’s instructions (Foot Science International, Christchurch, New Zealand). For the 3 mm flat insole, this moulding process will be one largely of slight compression of the material under weightbearing areas of the foot (i.e. it will not provide support to the arch of the foot or substantial contouring around the heel). Each participant will have their shoe insoles fitted to their athletic shoes and Defence-issued boots (i.e. two pairs of shoe insoles per participant) to maximise convenience and adherence to the interventions. All recruits will receive the same Defence-issued boots (Oliver Footwear Pty Ltd Structural Fire Fighter Boot, Model Number 20292) at the beginning of their 11 weeks of basic training (Figure 3).’

Even though the 3 mm flat insole (control) is being moulded it is expected to have a minimal ability to provide medial arch support as our research group has shown that similar control insoles (3 mm in thickness) provide no mechanical effects on the plantar midfoot, irrespective of whether they are flat or contoured [7].

Regarding the reviewer’s final point about data capture from medical officer/physio, we have mentioned in the manuscript that we will be accessing medical records and this will entail such information.

3. Is the interpretation (discussion and conclusion) well balanced and supported by the data?

Reviewer comment: The proposed study outline suggests that a robust strategy is being employed. However, consideration must be given to the aspect that any benefit from the moulded device maybe due to increased surface area contact over pressure rather, thus accommodative rather than altering functionality of the foot during gait/activity. This point is relevant given the normal definition of orthoses versus insoles.

Authors’ response: Formthotics® foot orthoses have been shown shown to affect lower limb muscle activity, kinetics and kinematics [3-6]. As such, they have been shown to act more than just an accommodative device and can be defined as ‘foot orthoses’ capable of altering lower limb function.
4. Are the methods appropriate and well described, and are sufficient details provided to allow others to evaluate and/or replicate the work?

Reviewer comment: Given the assessors are “blinded” further detail should be provided as to how this is being undertaken. Given the variety of Formthotics models (the website suggests >20) the paper should specify which device has been selected and the underpinning rationale, thus allowing future replication.

Authors’ response: Thank you, we have provided additional detail in the manuscript to clarify how assessor blinding is being achieved. It now reads: ‘Once all baseline measures have been taken, a therapist (separate investigator) located in an adjacent room (with no view of the participants) will allocate participants to one of the two groups (using the allocation system outlined in the manuscript). The therapist will fit and heat the allocated insoles into the participant’s footwear. Once the insoles have been heated, the therapist will place the participant’s footwear on a table outside of their room for the blinded assessor. The assessors, unaware of the insole allocation, will collect the participant’s footwear and advise the participants to wear their footwear for several minutes to allow moulding.’

Regarding the model of Formthotics used, we have now provided the model details in the ‘Interventions’ section. It now reads as follows: ‘Participants will be randomised to one of two groups: (i) a control group that will receive a pair of 3 mm flat insoles, or (ii) an intervention group that will receive a pair of Formthotics® prefabricated foot orthoses (Model: Original Single Medium) (Figure 2). Both interventions, collectively referred to as shoe insoles, will: be manufactured by the same company (Foot Science International, Christchurch, New Zealand), be full-length insoles made from the same material (140 kg/m³ single density, closed cell polyethylene foam), and will have the same branding (i.e. company logo).’ In addition, we have provided multiple images of the interventions – please refer to Figure 2. We have provided all available information about the orthotic intervention and it is the authors’ belief that anyone wanting to replicate the study could do so.

Regarding the justification/rationale of the selected experimental foot orthosis, and as mentioned in the discussion of the manuscript, it was selected for this trial for four main reasons. Firstly, prefabricated foot orthoses were considered more practical than customised foot orthoses as they can be issued to participants immediately, which is preferable in defence force populations. Secondly, prefabricated foot orthoses are relatively inexpensive compared to customised orthoses. This is an important consideration, as if this study demonstrates that foot orthoses can prevent injuries, cost effectiveness is likely to be a factor when deciding whether foot orthoses become standard issue for defence force recruits. Thirdly, the specific prefabricated foot orthosis (Formthotics®, Foot Science International, Christchurch, New Zealand) was selected as similar devices have been used in large randomised trials with few orthotic-related adverse events being reported [1, 2, 8]. The selected orthosis is made from polyethylene foam and a similar trial reported fewer orthotic-related participant drop-outs in those assigned to an orthosis made from a foam-based material (9%) compared to a semi-rigid plastic (37%) [9]. Such factors are important because minimising adverse events and ensuring the orthosis is comfortable is particularly important in this trial as the naval recruits will undertake rigorous activity within days of receiving their allocated shoe
insoles. Fourthly, the selected orthosis is commercially available and widely used in clinical practice, which may allow them to be readily utilised in naval populations.

5. **What are the strengths and weaknesses of the methods?**

**Reviewer comment:** See previous comment re extrapolation of data. In addition, further information regarding boot construction (it is assumed that new boots are issued at the same point for all recruits) and lacing styles are both standardised.

**Authors’ response:** This is correct, the recruits will wear standardised boots (see Figure 3). To provide the readers with more information and clarify this point, we have added the following sentence to the manuscript: ‘All recruits will receive the same Defence-issued boots (Oliver Footwear Pty Ltd Structural Fire Fighter Boot, Model Number 20292) at the beginning of their 11 weeks of basic training (Figure 3).’

One of the benefits of a parallel-group randomised controlled trial is that the effect of potential confounders, such as recruits lacing their boots differently, will be minimised by the study design. That is, the effects of such issues are largely cancelled out because they occur in both groups at the same time. In addition, our statistical analysis, utilising the ANCOVA analysis technique also adjusts for any baseline differences in the outcomes of interest. Therefore, all of these issues have already been controlled for by the authors; recruits are treated exactly the same no matter which group they are allocated to and our statistical analysis will control for extraneous confounders.

6. **Can the writing, organization, tables and figures be improved?**

**Reviewer comment:** Identification of insole/orthoses models and confirmation of boot style for naval recruits.

**Authors’ response:** As stated above, we have provided additional information regarding insole and boot models and we have provided images of each. We believe that these are now easily identified.

7. **When revisions are requested.**

**Reviewer comment:** The paper appears to be of interest, pertinent and displays a sound rationale. However, the above mentioned points should be clarified to support study design, data and potential conclusions.

**Authors’ response:** Thank you, we feel we have adequately addressed the above points from the reviewer.

8. **Are there any ethical or competing interests issues you would like to raise?**

**Reviewer comment:** The study appears to address all ethical issues and details them very clearly. It may be beneficial to state if the devices were supplied by Formthotics free for the purpose of the study and who retains the right to publish data. This is particularly relevant given the company concerned uses previous papers on their website.

**Authors’ response:** Thank you. This issue was addressed previously in the acknowledgements section and it reads as follows: ‘The foot orthoses and flat insoles will be donated by Foot Science...’
International Ltd, Christchurch, New Zealand. Foot Science International were not involved in the design of the trial, and will not be involved in the conduct, data analysis and interpretation of the findings of the trial.'
Reviewer 2: Trevor D Prior

Reviewer's report:

'Foot orthoses for the prevention of lower limb overuse injuries in naval recruits: study protocol for a randomised controlled trial'

Reviewer comment: This study protocol is well written and presented and appears suitably designed to test the hypotheses.

There are sufficient details to allow replication although some clarification of terminology is required which I have detailed below.

Authors’ response: Thank you. We have responded to the comments requiring ‘clarification of terminology’ below.

Major compulsory revisions

Reviewer comment 1: The paper evaluates the ‘use of foot orthoses’. However, the variability in design / materials and prescription protocols is so wide it is important that the orthoses being evaluated are accurately described. The authors have sufficiently explained the choice of device utilised based on ease, cost effectiveness etc. and should accurately describe the device, particularly in the title. Whatever results they obtain will be relevant to this specific device.

It would be of benefit if there were commonly used descriptions of differing devices but a description such as ‘personalised / modified / heat moulded preformed EVA orthoses would be a more accurate description. Alternatively, they could state the product in the title.

Authors’ response: Thank you, we agree that the results we observe will be relevant to the orthotic intervention under investigation and we feel this is acknowledged in the manuscript. The proposed intervention meets the definition of foot orthoses as described by the Prescription Foot Orthotic Laboratory Association (PFOLA, http://www.pfola.org/) as it is ‘an in shoe device that braces, supports, or protects the foot or part of the foot’. We have used the term ‘prefabricated foot orthoses’ throughout the abstract and manuscript so the style of ‘foot orthoses’ under investigation should be clearly obvious to readers. It is also clear in the methods section that the foot orthoses are heat moulded. Therefore, the authors propose that the term ‘foot orthoses’ is used in the title as the intervention meets this definition (irrespective of whether it is heat moulded, custom-made, prefabricated, made from polyethylene etc.), as defined by PFOLA, and additional information about the foot orthoses is provided throughout the manuscript. Also, the type of orthotic device is clearly outlined in the abstract for readers to evaluate. Additionally, ‘foot orthoses’ is a Medical Subject Heading (MeSH, https://www.nlm.nih.gov/mesh/meshhome.html) used by databases for indexation, so we believe using this term will allow the manuscript to be indexed appropriately using ‘foot orthoses’ in the title. Finally, this style of orthotic intervention has been used in several previous peer-reviewed publications and the term ‘foot orthoses’ is most frequently used in the title, abstracts and manuscripts to describe the intervention under investigation [3-6].

In additional to the above points, this trial has been registered (Australian New Zealand Clinical Trials Registry: ACTRN12615000024549) with the term ‘foot orthoses’ in the title so we would refer to
keep the terminology in the titles as consistent as possible. Finally, regarding the title, we feel it provides sufficient information to provide an indication of the article’s content, without providing additional/excessive information which is already provided in the abstract & manuscript e.g. more information about the orthoses, participants, study setting etc.

**Reviewer comment 2:** Similarly, the authors also provide a good reasoning regarding the choice of the control intervention which can be a contentious issue. I believe they have justified the device utilised but some confusion could remain.

In their justification, they quote a paper that evaluates a small range of sham orthoses (reference 50). However, in this reference, the 3 sham orthoses were described as:

1. Contoured polyethylene sham foot orthosis
2. Contoured ethylene vinyl acetate (EVA) sham foot orthosis
3. Flat ethylene vinyl acetate (EVA) sham foot orthosis

In the paper being reviewed, the flat insole is to be moulded to the subject’s foot within the shoe and thus most closely resembles the contoured EVA device rather than the flat device. Given that they have used the above paper as justification for their choice, they should be consistent with the terminology. It will also remove the possibility of confusion or misunderstanding and enhance the ability to replicate the study.

**Authors’ response:** Thank you for raising this point. In consideration of the reviewer’s comments we have amended a sentence in the discussion to be clearer on our justification of the control insole. The sentence now reads as ‘…..a flat insole was selected as the control intervention as similar insoles, whether flat or contoured, have been shown to provide the same mechanical effects as a shoe alone in the midfoot region (reference 50)’.

The publication by McCormick and colleagues [7] investigated a variety of sham orthoses and found that both the contoured and flat EVA insoles provided no mechanical effect on the medial midfoot. This was considered important as one of the major modes of how foot orthoses are proposed to provide benefits is through increased loading of the plantar-medial midfoot. In our trial, we elected to use a flat 3 mm insole (control intervention), which will be heat moulded and may become slightly contoured during this process. This moulding process will be one largely of slight compression of the material under weightbearing areas of the foot (i.e. it will not provide support to the arch of the foot or substantial contouring around the heel). However, given that our previous research into sham orthoses showed that both contoured and flat insoles provided no mechanical effects on the midfoot we believe it is appropriate to use the selected reference to justify the control insole used in this study.

Regarding the contentious issue regarding the use of a control insole, it helps mitigate against methodological issues that would potentially confound or bias the findings. Such issues are: (i) the placebo effect, (ii) ascertainment bias, and (iii) resentful demoralisation [10].

**Reviewer comment 3:** The authors acknowledge the difficulty in predicting which individuals will benefit from the prophylactic use of foot orthoses using characteristics such as foot posture.
However, they also report that they will be collecting data on foot posture, ankle joint dorsiflexion and lumbopelvic stability. This would suggest that they would be able to evaluate the effect of these factors on outcomes yet have not indicated that these will be incorporated in the analysis. This leaves some conclusions / possibilities:

a. The authors omitted this and it should be included.

b. The authors intend to analyse this and report in a separate paper. If this is the case, then these aspects of data collection should either be

i. removed as they have no relevance to this paper as it stands or

ii. acknowledge that this will be reviewed in a separate paper so that both papers can identify that they were evaluating the same group of subjects. In my opinion, this has great value when comparing results.

Authors’ response: Thank you for raising this point. We have elected to collect this information for several reasons. Firstly, we believe that much of this information will be used in the write-up of the trial to provide readers with a detailed description of the participant characteristics, which will aid practitioners when they are judging the generalisability of our findings to their patients. Secondly, this information will be able to be used to compare the baseline characteristics of the participants to ensure that confounders at baseline can be compared. Accordingly, we propose that this content remains in the manuscript.

References


